Rejection under 35 U.S.C. § 112, first and second paragraph

Reconsideration and withdrawal of rejection of claims 1,5,8 and 9 under 35 U.S.C. § 112 is respectfully requested.

On page two of the Office Action, the Examiner rejected claims 1, 5 and 8 under 35 U.S.C. § 112, first paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, and claims 1, 5 for failing to reasonably provide enablement.

Applicants respectfully traverse the rejection and request withdrawal of the rejection for the following reasons:

I. The office has asserted that "in Claim 1, 5 the term heteraryl "is a hug[e] area of chemistry that is hidden in the language of the claim, that requires specific conception by the reader."

To satisfy definiteness, an applicant "need only reasonably apprise those skilled in the art of the scope of the invention." *Miles Laboratories v. Shandon, Inc.*, 27 USPQ2d 1123 (Fed. Cir. 1993). Applicants respectfully submit that the term 'C_5-C_6 monocyclic heteroaryl ring containing one to three heteroatoms selected from O, S, and N' in Claims 1 and 5 is definite. Determining whether a patent claim is definite requires analysis of whether one skilled in the art would understand the bounds of the claim when read in light of the specification. Those skilled in the art will be able to determine immediately from the C_5-C_6 monocyclic heteroaryl definition starting on page 6, line 32, what the bounds of this claim are. The examiner asserts that "the possible combinations of any number of heteroatoms, in any combination, in multiple size rings is quite large". Even so, there are a finite number of ring structures that fit within the definition, and the bounds are clearly drawn. Further, breadth is not indefiniteness. *In re Robins*, 166 USPQ 552, 555 (C.C.P.A. 1970). Therefore, the fact that a genus is large does not preclude patentablility.

The Examiner also argues from a policy standpoint that "applicants should, in return for a 17/20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact." However, there is no requirement that an applicant must create every species within a claimed genus to properly obtain protection for that genus. Further, there are strong policy arguments why that would be the case. Take, for instance, the argument made by the Court of Customs & Patent Appeals in their

decision in *In re* Angstat 190 USPQ 214 at 218 (C.C.P.A.1976):

> Appellants have apparently not disclosed every catalyst which will work; they have apparently not disclosed every catalyst which will not work. The question, then, is whether in an unpredictable art, section 112 requires disclosure of a test with every species covered by a claim. To require such a complete disclosure would apparently necessitate a patent application or applications with "thousands" of examples or the disclosure of "thousands" of catalysts along with information as to whether each exhibits catalytic behavior resulting in the production of hydroperoxides. More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed. A potential infringer could readily avoid "literal" infringement of such claims by merely finding another analogous catalyst complex which could be used in "forming hydroperoxides."

II. The Examiner also asserts that adjacent O/O; O/S or S/S combinations ...are too unstable to be made", and that "applicants claim compounds which have not, yet, been made."

It is respectfully submitted that the Examiner provides no evidence of undue experimentation. Experimentation is not fatal; some experimentation is permissible "if it is merely routine ... or if the specification in question provides a reasonable amount of guidance...." *Johns Hopkins Univ. v. Cellpro, Inc.,* 47 USPQ2d 1705 (Fed. Cir. 1998). The specification clearly lays out 6 specific schemes and 11 generic schemes for production of compounds within the genus. It is not necessary for every embodiment to work for an invention to be enabled. In fact, claims can be valid even though they read on a "very large number of inoperative embodiments" so long as "a person skilled in the relevant art could determine which conceived of but not-yet-fabricated embodiments would be inoperative with no more effort than is normally required..." *In re Cook,* 169 USPQ 298 (C.C.P.A. 1971). Here, one skilled in the art would know that to put O-O and O-S in those positions would create an unstable compound, so the fact that non-operative embodiments may exist is a moot point.

III. The office has asserted that in Claim 8, no one can determine what is encompassed by the term 'prodrug'.

Applicants respectfully disagree with this assertion and request withdrawal of this objection for the following reasons:

The term prodrug is well known in the art as a compound designed to undergo a predictable metabolic modification, specifically, one that converts an inactive precursor into an active drug. Further, the office has allowed 780 such patents with the term prodrug/pro-drug in the claims since 1996, indicating an acceptance of the term. Finally, the doctrine of equivalents has been applied to find infringement when a substituted compound or ingredient converts *in vivo* or *in situ* to a compound or ingredient called for by a patent claim, and performs the same function as that of the claimed product. *Ortho Pharmaceutical Co. v. Smith*, 22 USPQ2d 1119 (Fed.Cir. 1992).

Rejection under 35 U.S.C. § 101

I. The Examiner has asserted that Claim 9 "does not relate to the real world of commerce". Further, the Examiner has asserted that "[t]he Board of Appeals and the C.C.P.A. have held that even though the specification does not mention human use specifically, the Patent Office is not precluded from finding an inference of human use and require proof thereof, when such use is a medical nature for the treatment of a serious disease."

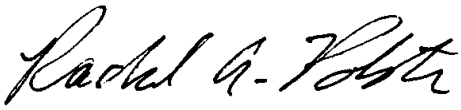
Applicants respectfully disagree with this assertion and request withdrawal of this objection for the following reasons:

Applicants respectfully submit that the Examiner has not presented a *prima facie* case for lack of a "real world" utility. MPEP 2107 contrasts the situation where an applicant merely indicates that a compound may be useful in treating unspecified disorders with "the situation where applicant discloses a specific biological activity" (in this instance, the inhibition of the alphav-beta3 integrin) "and reasonably correlates that activity to a disease condition" (in this instance, the specification provides that avb3 plays a role in various conditions

or disease states including tumor metastasis, solid tumor growth (neoplasia), osteoporosis, Paget's disease, humoral hypercalcemia of malignancy, angiogenesis, including tumor angiogenesis, retinopathy, including macular degeneration, arthritis, including rheumatoid arthritis, periodontal disease, psoriasis and smooth muscle migration (e.g., restenosis arhterosclerosis), antivirals, antifungals, and antimicrobials). Literature supporting the correlation between the avb3 integrin and these disease states was further provided in the specification. Therefore, applicants have provided a specific, credible real world utility for Claim 9.

In view of the foregoing remarks, it is respectfully submitted that all claims now active in the present application are in condition for allowance. Therefore, passage of the application and claims to issue is respectfully requested.

Respectfully submitted,



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